

**WHAT IS CLAIMED IS:**

1. A nucleic acid molecule comprising a sequence encoding a recombinase and a signal sequence recognized by said recombinase.

2. A nucleic acid molecule comprising at least a first signal site and a second signal site and a recombinase gene operably linked to an expression control sequence, said first and second signal sites being positioned to mediate excision of a sufficient portion of either the recombinase gene or the expression control sequence to extinguish recombinase activity when the first and second signal sites are contacted with a recombinase.

3. The nucleic acid molecule of claims 1 or 2, wherein said nucleic acid molecule is included in a retroviral vector and said signal sequence is inserted into a retroviral long terminal repeat of said vector.

4. The nucleic acid molecule of claim 3, wherein said signal sequence is inserted into the U3 region of the 3' retroviral long terminal repeat of said vector, or the U5 region of the 5'LTR, or the R region.

5. The nucleic acid molecule of claims 1 or 2, wherein said recombinase is selected from the group consisting of a cre recombinase and a Flp recombinase and the signal site is selected from the group consisting of lox sites and FRT sites.

6. The nucleic acid molecule of claim 1, wherein said nucleic acid molecule comprises two signal sequences that are recognized by said recombinase and are positioned with respect to said sequence encoding said recombinase so that recombination by said recombinase inactivates or decreases expression of said recombinase.

7. The nucleic acid molecule of claim 6, wherein said signal sequences flank said sequence encoding said recombinase or a positive regulatory element of said sequence encoding said recombinase.

8. A cell comprising the nucleic acid molecule of any one of claims 1, 2 or 6.

9. The cell of claim 8, further comprising a second nucleic acid molecule comprising a target gene and signal sequences recognized by said recombinase.

10. The cell of claim 9, wherein said recombinase, when expressed in said cell, excises or inverts a sequence in said second nucleic acid molecule that is located between said signal sequences in said second nucleic acid molecule, and the excision or inversion results in modulation of expression of said target gene.

5 11. The cell of claim 10, wherein said signal sequences in said second nucleic acid molecule are in direct orientation with respect to one another.

12. The cell of claim 11, wherein said signal sequences in said second nucleic acid molecule flank said target gene, so that expression of said recombinase results in excision of said target gene, and inactivation of expression of said target gene.

10 13. The cell of claim 11, wherein said signal sequences in said second nucleic acid molecule flank a positive regulatory element of said target gene, so that expression of said recombinase results in excision of said positive regulatory element, and inactivation of expression of said target gene.

15 14. The cell of claim 11, wherein said signal sequences in said second nucleic acid molecule flank a negative regulatory element of said target gene, so that expression of said recombinase results in excision of said negative regulatory element, and activation of expression of said target gene.

15. The cell of claim 9, wherein said signal sequences in said second nucleic acid molecule are in an inverted orientation with respect to one another.

20 16. The cell of claim 15, wherein said signal sequences in said second nucleic acid molecule flank an inverted positive regulatory element of said target gene or an inverted coding region of said target gene, so that expression of said recombinase results in inversion of said inverted positive regulatory element or inversion of said inverted coding region, and activation of expression of said target gene.

25 17. The cell of claim 15, wherein said signal sequences in said second nucleic acid molecule flank an inverted negative regulatory element of said target gene or a coding region of said target gene, so that expression of said recombinase results in inversion of said

inverted negative regulatory element or inversion of said coding region, and inactivation of expression of said target gene.

18. The cell of claim 8, wherein said signal sequences in said nucleic acid molecule comprising said sequence encoding said recombinase flank said nucleic acid sequence encoding said recombinase.

19. The cell of claim 8, wherein said signal sequences in said nucleic acid molecule comprising said sequence encoding said recombinase flank a positive regulatory element of said nucleic acid sequence encoding recombinase.

20. The cell of claim 9, wherein said nucleic acid molecule comprising said sequence encoding said recombinase and said second nucleic molecule are present in the same vector.

*Sub Bb* 21. The cell of claim 9, wherein said nucleic acid molecule comprising said sequence encoding said recombinase and said second nucleic acid molecule are present in separate vectors.

15 22. A transgenic, non-human animal comprising the cell of claim 8 or 9.

23. The transgenic, non-human animal of claim 22, wherein said target gene encodes a protein to be made in a targeted secretion of the animal.

24. A transgenic plant comprising the cell of claim 8 or 9.

25. The transgenic plant of claim 24, wherein said plant comprises a first and a second tissue, and said sequence encoding said recombinase is expressed in said first tissue, but not in said second tissue.

26. The transgenic plant of claim 25, wherein said first tissue of said plant is edible and said second tissue of said plant is inedible.

27. A method for modulating a target gene in a cell, said method comprising introducing into said cell:

a first nucleic acid molecule comprising a region encoding a recombinase and signal sequences recognized by said recombinase, and

a second nucleic acid molecule comprising a target gene and signal sequences recognized by said recombinase, and

5       wherein said recombinase, when expressed in said cell, excises or inverts a sequence in said second nucleic acid molecule that is flanked by said signal sequences in said second nucleic acid molecule, and the excision or inversion results in modulation of expression of said target gene.

28. The method of claim 27, wherein said cell is in an animal.

10      29. The method of claim 28, wherein said animal is a mammal.

30. The method of claim 29, wherein said mammal is a human.

31. The method of claim 29, wherein said mammal is a mouse, a goat, a pig, or a cow.

15      32. The method of claim 27, wherein said target gene encodes a diagnostic or therapeutic agent.

33. The method of claim 27, wherein said cell is in a plant.

34. The method of claim 33, wherein said target gene encodes a disease resistance protein.

20      35. The method of claim 33, wherein expression of said recombinase is induced in said plant within one week prior to harvest.

36. The method of claim 33, wherein said plant comprises a first and a second tissue, and said recombinase is expressed in said first tissue, but not in said second tissue.

37. The method of claim 35, wherein said first tissue of said plant is edible and said second tissue of said plant is inedible.

38. The method of claim 27, wherein said signal sequences in said second nucleic acid molecule are in direct orientation with respect to one another.

39. The method of claim 38, wherein said signal sequences in said second nucleic acid molecule flank said target gene, so that expression of said recombinase results in 5 excision of said target gene, and inactivation of expression of said target gene.

40. The method of claim 38, wherein said signal sequences in said second nucleic acid molecule flank a positive regulatory element of said target gene, so that expression of said recombinase results in excision of said positive regulatory element, and inactivation of expression of said target gene.

10 41. The method of claim 38, wherein said signal sequences in said second nucleic acid molecule flank a negative regulatory element of said target gene, so that expression of said recombinase results in excision of said negative regulatory element, and activation of expression of said target gene.

15 42. The method of claim 27, wherein said signal sequences in said second nucleic acid molecule are in an inverted orientation with respect to one another.

43. The method of claim 42, wherein said signal sequences in said second nucleic acid molecule flank an inverted positive regulatory element of said target gene or an inverted coding region of said target gene, so that expression of said recombinase results in inversion of said inverted positive regulatory element or inversion of said inverted coding region, and 20 activation of expression of said target gene.

44. The method of claim 42, wherein said signal sequences in said second nucleic acid molecule flank an inverted negative regulatory element of said target gene or a coding region of said target gene, so that expression of said recombinase results in inversion of said inverted negative regulatory element or inversion of said coding region, and inactivation of 25 expression of said target gene.

45. The method of claim 27, wherein said signal sequences in said first nucleic acid molecule flank said region encoding said recombinase.

46. The method of claim 27, wherein said signal sequences in said first nucleic acid molecule flank a positive regulatory element of said region encoding said recombinase.

47. The method of claim 27, wherein said first nucleic acid molecule and said second nucleic molecule are present in the same vector.

5 48. The method of claim 27, wherein said first nucleic acid molecule and said second nucleic acid molecule are present in separate vectors.

10 49. A method for excising a nucleic acid sequence from a cell, wherein said nucleic acid sequence is present in the cell and contains a recombinase gene operably linked to an expression control sequence and further contains a first signal site and a second signal site, the method comprising expressing a recombinase in the cell, wherein the recombinase catalyzes recombination between said first signal site and said second signal site, thereby excising a portion of the nucleic acid sequence from the genome located between the first and second signal sites, the first and second signal sites being positioned to mediate excision of a sufficient portion of either the recombinase gene or the expression control sequence so as to 15 extinguish recombinase activity when the first and second signal sites are contacted with the recombinase.

50. A library of cells comprising a long terminal repeat and a recombinase recognition site integrated into the genome of each of the cells.